

Appendix 2

APPENDIX 2. ADDITIONAL COMMENTS

Following are section-by-section comparisons between this proposed Guidance for Information for the Patient (the PPI) with the text of the FDA's Draft Guidance for Labeling for Healthcare Professionals and Patients and refers to specific section numbers in the PPI.

- I. List of the subject categories as stated in the FDA's Draft Guidance, each category followed by a list of the sections in the proposed PPI that deal with that subject.
- II. A section-by-section discussion of any differences between the proposed PPI and the FDA's Draft Guidance.
- III. Other general comments on other modifications, terminology and formatting.

I. FDA GUIDANCE CATEGORIES WITH CORRESPONDING PPI SECTIONS

BOXED WARNING-CIGARETTE SMOKING (not included)

PROPRIETARY NAME
(to be provided by manufacturer)

DESCRIPTION
1. About birth control Pills
2. How does the Pill work?

CLINICAL PHARMACOLOGY
(not applicable to *PPI*)

INDICATIONS AND USAGE
3. How well does the Pill work?

WARNINGS
5. Who should not take the Pill?

PRECAUTIONS
8. Can I take the Pill with other medicines
9. STDs (Sexually Transmitted Diseases)
16. What if I want to get pregnant?
17. Does the Pill cause birth defects?
18. What if I just had a baby?

ADVERSE EXPERIENCES

6. Can the Pill cause medical problems?
7. What side effects can I get from the Pill?

NON-CONTRACEPTIVE HEALTH BENEFITS

4. What are some advantages of taking the Pill?

OVERDOSAGE

19. What if a child takes any of the Pills?

DOSAGE AND ADMINISTRATION

(not applicable to PPI-See instructions, Section 10)

HOW SUPPLIED

10. What should I do when I start taking the Pill? (Sx. 10. 1- 10.2)

STORAGE

20. Where should I keep the Pills?

INSTRUCTIONS FOR USE

10. What should I do when I start taking the Pill?
11. What should I do if I miss any Pills?
12. Important reminders about missed Pills
13. Emergency Contraceptive Pills (ECPs)
14. What if I miss my monthly period?
15. What if I want to stop taking the Pill or change birth control methods?

II. DISCUSSION OF DISCREPANCIES BETWEEN THE PPI AND FDA DRAFT GUIDANCE, BY PPI SECTION NUMBER.

[Note: The only sections discussed here are those for which there are discrepancies.]

1. About Birth Control Pills [DESCRIPTION]

This section is an introduction to the labeling and is generally consistent with the current PPI.

2. How does the Pill work? [DESCRIPTION]

2.2 The term “fertilization” is used here; the Labeling for Health Care Professionals (LHCP) uses “penetration.”

3. How well does the Pill work? [INDICATIONS AND USAGE]

3.1 Acne prevention is not included here. It is in Section 4: Other advantages.

3.4 Table comparing effectiveness of methods:

Less effective methods that are very rarely prescribed at this time are excluded here; specifically, the cap, sponge, and Lactational amenorrhea method (LAM). Emergency contraceptive pills are discussed separately in Section 13.

The table on the effectiveness of various methods is included here;
However we recommend that it be dropped from the PPI. It is complicated

4. What are some advantages to taking the Pill? [NON-CONTRAC. BENEFITS]

4.4 Acne prevention is included here, not in Section 2.1
Osteoporosis is also added to the PPI and is included here.

5. Who should not take the Pill? [WARNINGS]

5.4 “If your doctor or clinic staff think the following problems are not too serious.. .” has been added.

6. Can the Pill cause medical problems? [WARNINGS]

6.2 Breast cancer: The warning about “starting the Pill under 20” is not included in the PPI.

6.4 The table “Warning Signs” has been added to this section.

Unexplained vaginal bleeding is included in Section 5.4 instead of Section 6.

7. What side effects can I get from the Pill? [ADVERSE EXPERIENCES]

7.3 Acne and cervical ectopia are not included.

8. Can I take the Pill with other medicines? [DRUG INTERACTIONS]

8.1 If you are taking other medicines:
-Ascorbic acid and acetaminophen are not included here.
-St. John’s Wort has been added.
-Individual medications affected by OCs are not listed here.

9. STDs (Sexually Transmitted Diseases) [PRECAUTIONS]

9.1 PID is not included.

- Physical examination is not included in this PPI.

10-18. NINE SECTIONS ON HOW TO TAKE THE PILL. [INSTRUCTIONS]

These 9 sections replace the LHCP's single section on "How to take the Pill" in order to make specific items of information easier to find.

10. What should I do when I start taking the Pill? [INSTRUCTIONS]

10.5 "Your sexual activity varies from week-to-week" is not included.

11. What should I do if I miss any Pills?

NOTE: This remains the most difficult part of the PPI for OC users to understand.

11.1-I 1.5. The instructions for handling missed pills from 21- and 28-day Pills have been combined except when referring to the 4th, hormone-free, week. The only difference, between the two regimens is that the 28-day packs include 7 placebo "reminder" pills to be taken in the 4th week of the cycle whereas the 21-day packs include no pills for the 4th week.

The order of the instructions for multiple missed Pills has been changed, to reflect the sequence of actions, instead of starting with "Most Important: Use condoms.. ." (INSTRUCTIONS in the LHCP)

In addition, this proposed PPI refers to "condoms" alone instead of "condoms or other back up methods, including.. ." in its instructions for handling missed pills for two reasons:

- 1) Condoms are the only barrier method and the only back up method many OC users are familiar with.
- 2) Condoms are the only method recommended to prevent STDs and HIV.

11.6 The instructions for handling vomiting have been changed to reflect the fact that missing a single Pill does not increase the chance of pregnancy. Diarrhea is not included.

12. Important reminders about missed Pills [MOST IMPORTANT TO REMEMBER]

The order of the instructions has been changed, to reflect the sequence of actions rather than first stating the importance of using condoms.

13. Emergency Contraceptive Pills (ECPs) [NEW SECTION]

This new, separate section has been added to emphasize the value and timing of ECP use if unprotected sex has occurred.

18. What if I just had a baby?

[PRECAUTIONS]

Under “If you are breast feeding,” the following statement has been added:
“It is safest to wait until you have finished breast feeding to start taking the Pill.”

[NOTE: We did not include PEDIATRIC USE (Sx. 8 in the LHCP) in this PPI.]

19. What if a child takes any of the Pills?

[OVERDOSAGE]

This PPI does not include information on the chance of nausea and withdrawal bleeding in females because of taking multiple pills.

III. OTHER GENERAL COMMENTS /RECOMMENDATIONS

1. Further modifications of the PPI by the FDA or manufacturers

We recognize that the FDA and manufacturers may want to modify some of the wording and/or change certain details of this document. We do request however that any modifications keep in mind that this text does reflect extensive interviewing with OC users and consultation with more than 40 medical and readability experts.

2. Terminology

- 1) While recognizing that “health care provider” is the term used in the LHCP and many other health information materials. That term has been replaced throughout this PPI with the phrases “doctor or clinic” or “doctor or clinic staff” because of the consensus among OC users interviewed that they preferred the latter wording.
- 2) In Sections 4-7 of this document the lay term for a medical condition is placed before the medical term, again based on the preference of the OC users interviewed and the expert reviewers on readability. For example, “cancer of the uterus (endometrial cancer).”

3. Formatting

We strongly recommend that:

- 1) at least 12-point type be used, black lettering on a white background
- 2) there be sufficient white space to make reading easier
- 3) upper and lower case letters be used rather than all caps
- 4) headings of each section be in a larger font, in bold letters and stated as questions
- 5) all sections be numbered for easy reference and discussion between provider and patient

Draft Guidance for Industry on Combined Oral Contraceptives-Labeling for Healthcare Providers and Patients: COMMENTS by the Family Planning Council, Philadelphia PA, February 15, 2001